

Compressed Air Massage Hastens Healing of the Diabetic Foot

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ABSTRACT

Background: The management of diabetic foot ulcers remains a problem. A treatment modality that uses compressed air massage has been developed as a supplement to standard surgical and medical treatment. Compressed air massage is thought to improve local tissue oxygenation around ulcers. The aim of this study was to determine whether the addition of compressed air massage influences the rate of healing of diabetic ulcers.

Methods: Sixty consecutive patients with diabetes, admitted to one hospital for urgent surgical management of diabetic foot ulcers, were randomized into two groups. Both groups received standard medical and surgical management of their diabetes and ulcer. In addition, one group received 15–20 min of compressed air massage, at 1 bar pressure, daily, for 5 days a week, to the foot and the tissue around the ulcer. Healing time was calculated as the time from admission to the time of re-epithelialization.

Results: Fifty-seven patients completed the trial; 28 received compressed air massage. There was no difference in the mean age, Wagner score, ulcer size, pulse status, or peripheral sensation in the two groups. The time to healing in the compressed air massage group was significantly reduced: 58.1 ± 22.3 days (95% confidence interval: 49.5–66.6) versus 82.7 ± 30.7 days (95% confidence interval: 70.0–94.3) ($P = 0.001$). No adverse effects in response to compressed air massage were noted.

Conclusions: The addition of compressed air massage to standard medical and surgical management of diabetic ulcers appears to enhance ulcer healing. Further studies with this new treatment modality are warranted.

INTRODUCTION

IT IS ESTIMATED that there are nearly 200 million people with diabetes worldwide, with 3.2 million deaths a year attributable to complications of diabetes.^{1,2} There is also an increasing incidence of type 2 diabetes mellitus, with more adolescents now developing type 2

diabetes. This may be linked to the growing problem of obesity.³ It is further estimated that there are approximately 20.8 million Americans who have diabetes, a third of whom do not know that they suffer from the problem.^{4,5}

Approximately 50% of individuals with diabetes suffer from peripheral sensory neuropathy, which is a precursor of diabetic ulceration,

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and 15–25% of those with diabetes will develop a foot ulcer at some time during their life.^{4,6,7} Of these, six to eight patients with diabetes per thousand will require an amputation as a result of vascular disease, peripheral neuropathy, and problems with wound healing.^{5,8}

The management of diabetic foot ulcers remains a problem, and vigilant foot care is the cornerstone of prophylaxis.⁹ Once a pedal ulcer has developed, treatment includes unloading of the area, metabolic control, debridement, regular wound toilet, appropriate antibiotic therapy if necessary, and assessment of the adequacy of local blood supply to allow healing.¹⁰ Numerous dressings have been advocated for use at different phases of ulcer healing, and human skin substitutes, growth factors, bone marrow-derived stem cells, and skin grafts are all used.^{11,12} In addition, there are a number of adjunctive modalities that have been used, with varying degrees of success, in the management of diabetic ulcers. These include electrical stimulation,¹³ topical oxygen therapy,¹⁴ hyperbaric oxygen therapy,¹⁵ ultrasound,¹⁶ phototherapy,¹⁷ larval therapy,¹⁸ and vacuum-assisted closure.¹⁹

Devices for compressed air massage were developed by Courtin²⁰ for cosmetic use in the 1960s. Recently, renewed interest in the modality suggests that it may improve local circulation and that it has the potential to be used to supplement standard surgical and medical treatment of diabetic ulcers. A stream of compressed air is directed onto an affected area through an applicator head. The head may have multiple pinholes, which when stroked over an area provides a massage that equates to superficial effleurage massage, or a single 5-mm hole, which gives a deep effleurage massage. Compressed air massage is thought to improve local blood flow and reduce edema, thereby effectively improving tissue oxygenation.^{21,22}

The aim of this prospective, randomized, controlled study was to determine whether the addition of compressed air massage influences the rate of healing of patients presenting to a surgical service with a diabetic foot. An abstract of the preliminary results has been published.²³

SUBJECTS AND METHODS

Sixty consecutive patients with diabetes, admitted to the surgical unit at RK Khan Hospital (Durban, South Africa) with infected, non-ischemic foot ulcers (at least one pedal pulse palpable), were randomized into one of two groups. All patients were taken to the operating theater where they underwent radical debridement of all necrotic tissue and minor amputation, if necessary, to eliminate sepsis. Metabolic control was sought before surgical debridement and maintained in the postoperative period. Both groups received standard medical and surgical management of their diabetes and ulcer thereafter. This included soluble insulin on a sliding scale based on glucometer readings during the perioperative phase, a course of postoperative antibiotics, strict bed rest, daily lavage of the wounds with saline, and dressing with an antiseptic cream. Wounds were inspected daily, and chemical or surgical debridement was performed as necessary until the wound was healed. Healing was defined as re-epithelialization of the wound or successful split skin graft. Healing time was calculated as the time from initial surgical procedure to the time of re-epithelialization or successful skin graft.

In addition to the standard treatment, the compressed air massage group received 15–20 min of compressed air massage, at 1 bar (100 kPa) pressure, daily, for 5 days a week until the wound was healed or the patient had undergone a skin graft. Treatment was to the foot and the tissue around the ulcer and not to the ulcer bed.

Compressed air massage

The apparatus consists of an electrical air compressor, feeding air into a commercial apparatus (Jet Therapy[®], Durban, South Africa), which is made up of two reservoir tanks, medical air filters, a pressure regulator valve, pressure tubing, and several different applicator heads. Compressed air, at pressures of 4–7 bar (400–700 kPa), passes from the compressor into the first reservoir tank, where it is filtered to remove any particulate matter. A regulator valve controls the pressure at which the compressed

air is released from the first reservoir tank into the second reservoir tank and subsequently through compression tubing to an applicator head. Treatment involves massaging the skin of the foot and lower leg with the metal applicator head, and the stream of compressed air that passes through the applicator head supplements the massage. In this study an applicator head with multiple small holes was used to provide an effleurage-like massage.

After surgical debridement, wounds were measured longitudinally and transversely and photographed, and a tracing of the wound was made. Wound area was determined by planimetry.²⁴

This study was undertaken with the approval of the Bio-ethics Committee of the University of KwaZulu-Natal, and all patients gave signed, informed consent.

Data are expressed as the mean and 1 SD, and the 95% confidence interval (CI) values were provided where appropriate. Comparison of means was by two-tailed unpaired *t* test. The Mann-Whitney test was used to compare Wagner scores, and correlations were performed using Pearson's correlation test. Alpha was set at 5%.

RESULTS

Fifty-seven patients completed the study, 29 in the standard treatment group and 28 in the compressed air massage group. One patient in each group died of a myocardial event during the trial, and one patient in the treatment group was lost to follow-up after discharge from the hospital. There was no significant difference in the mean age of the control group (55.3 ± 9.0 years; 95% CI: 52.0–58.6) and the treatment group (51.5 ± 7.6 years; 95% CI: 48.7–54.4). Eight patients in each group had type 1 diabetes.

There was no difference between groups for the presence of co-morbidities such as hypertension, a history of chronic cardiac failure, or ischemic heart disease, nor was there a difference between groups for light touch, pain, vibration sense, or pulse status in the affected limb. The mean Wagner score of the control

group was 2.6 with a median of 3, and in the treatment group it was 2.9 with a median of 3 ($P = 0.44$).

Wound size at inception was $2,668 \pm 2,172.5$ mm² (95% CI: 1,825.5–3,510.4 mm²) for the control group and $3,000.0 \pm 3,267.6$ mm² (95% CI: 1,732.8–4,267.2 mm²) for the treated group ($P = 0.66$). The treatment group showed an overall reduction in time to healing of 25 days, or 30.1% ($P = 0.001$). Ten patients in the control group and nine in the treatment group underwent split skin grafting. Fifteen patients in the control group and 14 in the treatment group underwent an amputation of toes or part of the forefoot. The mean time to healing and ulcer sizes at inception for both groups of patients and the subgroups that underwent skin grafting or amputation are shown in Table 1. There was no statistical difference in the size of ulcers in the two groups at inception. Healing was significantly faster in the treatment group and in the subsets of treated patients who either underwent split skin grafting or who had an amputation. Patients in the treated group underwent split skin grafting after 30.8 ± 14.7 (95% CI: 18.6–43.3) days as opposed to 45.1 ± 12.2 (95% CI: 36.4–53.8) days ($P = 0.39$) in the control group. Ulcers that were skin-grafted were significantly larger than those that were not grafted in both the control group ($P < 0.0001$) and treatment group ($P = 0.0003$). In both groups, the time to healing was not different between the skin-grafted and non-grafted ulcers.

No correlation was found between Wagner grade and time to healing, Wagner grade and ulcer size, and ulcer size and time to healing in either the control or treatment group, nor was there any correlation for the subsets of patients who did or did not undergo skin grafting in either group. Similarly, no correlations were found for these parameters, based on the presence or absence of sensory changes in the affected limb in both the control and treatment groups and the subsets based on skin grafting.

The Wagner grade, ulcer size, and time to healing were not related to the degree of sensory changes noted. The reduction in time to healing in the treatment group as a whole and for both the skin-grafted and non-grafted ul-

TABLE 1. CHARACTERISTICS OF SUBJECTS IN EACH GROUP AND TIME TO HEALING OF DIABETIC ULCERS IN THE PATIENTS IN THE CONTROL AND COMPRESSED AIR MASSAGE-TREATED GROUPS

	<i>Control</i>		<i>Air massage</i>		P
	<i>Mean</i>	<i>95% CI</i>	<i>Mean</i>	<i>95% CI</i>	
Total number of patients	29		28		
Time to healing (days)	82.7 ± 30.7	70.0–94.3	58.1 ± 22.3	49.5–66.6	0.001
Ulcer size (mm ²)	2,668 ± 2,172	1,826–3,510	3,000 ± 3,267	1,733–4,267	0.656
Subgroup					
Number of patients	19		19		
No skin graft (days)	85.1 ± 32.1	69.6–100.6	59.8 ± 21.4	49.5–70.2	0.007
Ulcer size (mm ²)	1,442 ± 930	980–1,904	1,604 ± 1,074	1,087–2,122	0.627
Subgroup					
Number of patients	10		9		
Skin graft (days)	79.8 ± 28.2	41.0–79.0	53.3 ± 24.9	34.2–72.5	0.045
Ulcer size (mm ²)	4,875 ± 2,027	3,425–6,325	5,946 ± 4,365	2,591–9,301	0.494
Subgroup					
Number of patients	15		14		
Amputation (days)	77.3 ± 27.0	62.3–92.2	57.2 ± 24.8	43.5–70.9	0.043
Ulcer size (mm ²)	3,236 ± 1,903	2,138–4,335	2,882 ± 1,829	1,829–3,938	0.494
Subgroup					
Number of patients	11		10		
No SSG or amputation (days)	96.9 ± 33.2	74.6–119.2	61.9 ± 21.6	46.5–77.4	0.011
Ulcer size (mm ²)	1,199 ± 954	558–1,840	1,346 ± 906	698–1,995	0.722

Data are expressed as mean ± 1 SD values and the 95% CI. SSG, split skin grafting.

cers in the treatment group was independent of sensory status.

No adverse effects in response to compressed air massage were noted during the treatments. Patients commented that the expanding air caused cooling, and some indicated that it reduced pain associated with peripheral neuropathy.

DISCUSSION

The two groups of patients appeared to be similarly matched for ulcer size, vascular status, sensory changes, and co-morbidities. The main finding of this study is that the addition of compressed air massage to standard medical and surgical management of infected diabetic ulcers presenting for emergency surgery significantly reduces time to healing by approximately 25 days. Healing time was improved by 22 days in ulcers that healed by re-epithelialization without amputation or skin graft, and by 26 days in those that were skin-grafted. The average time to healing of patients in the control group is similar to other reported studies.²⁵

Ulcer size was on average similar in the con-

trol and treatment groups, and in both groups, ulcers that were skin-grafted were significantly larger than those that were not grafted. Skin-grafted ulcers in the compressed air massage group healed significantly sooner than skin-grafted ulcers in the control group. Within the two groups, although the time to healing of the skin-grafted ulcers was reduced, this was not significant. The time to skin graft was less in the compressed air massage group, but the difference was not significant. These findings suggest that compressed air massage may promote granulation and ready the graft bed more rapidly than conventional treatment.

In this study all patients had at least one palpable pedal pulse in the affected foot, and vascular status was not a determinant of healing time in either group. Similarly, sensory status was also not related to ulcer size or healing time in either group or in the subsets of patients who were skin-grafted or not skin-grafted.

Very little is known about the mode of action of compressed air massage therapy. Possible mechanisms of action include (1) an intermittent positive pressure treatment effect reducing superficial edema, with subsequent improvement of cellular oxygenation due to re-

duced oxygen diffusion distance, (2) direct stimulation of local skin blood flow,^{21,22} (3) skin cooling during treatment²² with reflex vasodilatation and improved blood flow on rewarming, and (4) localized tissue damage inducing an inflammatory response.²⁶

Compressed air massage has been shown to significantly improve local skin blood flow measured using laser Doppler fluxmetry. The improvement in skin blood flow is apparent up to 4 cm away from the site of treatment. During treatment, expansion of the compressed air results in skin cooling of about 5°C. Skin blood flow returns to normal when treatment stops, and there is no evidence of reflex vasodilation within 15 min of treatment.²² Compressed air massage may directly stimulate skin blood flow by increasing the velocity of blood flow and compressing vessels under the air stream. This would be expected to increase shear stress at the luminal surface of endothelial cells with a resultant increase in nitric oxide production and vessel dilation.²⁷ The increase in skin blood flow measured during treatment using laser Doppler fluxmetry would support this. It would, however, be expected that when treatment stops, nitric oxide-related dilation would continue for a brief period because of up-regulation of endothelial nitric oxide synthase. The return of skin blood flow to normal levels within a minute of stopping treatment may reflect the fall in skin temperature during treatment, with closure of thermoregulatory arteriovenous shunts.²⁸ It should be noted that laser Doppler fluxmetry is considered to measure blood flow to the depth of the thermoregulatory arteriovenous shunts, and that the increase in skin blood flow reported may not constitute an improvement in nutritional skin blood flow.²⁹

In a series of electron microscopy studies in an animal model, compressed air massage resulted in significant dilation of skeletal muscle capillaries within 10 min of treatment that was still present 24 h later.²¹ This dilation might be explained by treatment either imparting a systemic effect that lasts at least 24 h, or possibly an inflammatory response following minor muscle trauma during treatment.

Edema is a feature of the diabetic foot. It is a consequence of increased capillary filtration associated with diabetic microangiopathy.^{30,31}

The study by Reiber et al.³² on the causal pathways leading to diabetic ulcers detailed the critical triad of neuropathy, minor foot trauma, and foot deformity as the major causal factors, with edema the next most common factor. Peripheral limb edema has also been identified as a significant risk factor for amputation in patients with diabetic ulcers.³³

Compression in different forms has been advocated for the management of limb edema and in the management of high perfusion microangiopathy in patients with diabetes. Elastic stockings reduce capillary leakage and edema formation and may retard the progression of the diabetic microangiopathy.³⁴ Layered compression bandaging has been used for diabetic ulcers in patients with adequate arterial circulation,³⁵ as have total contact boots,^{36,37} pneumatic pedal devices,³⁸ and pump and wrap systems.³⁹

Impaired peripheral vascular function is also a risk factor for the development of diabetic ulcers. Low transcutaneous oxygen pressure (TcPO₂), an indicator of the adequacy of skin perfusion, has been found to be an independent predictor of ulceration.⁴⁰ TcPO₂ is influenced by edema,^{41,42} and can be improved by reducing edema.⁴³ It has also been demonstrated that decompression of the infected diabetic foot, by drainage and or local amputation, also improves TcPO₂.⁴⁴

Compressed air massage can be considered to be a form of localized, intermittent compression therapy. The pressures generated by the applicator head during massage and by the stream of compressed air on the skin are transmitted to the deep tissues. Average pressures of 54 mm Hg were obtained in subcutaneous fat overlying muscle, at a treatment pressure of 1 atmosphere.⁴⁵ This is higher than pressures used at the foot in pneumatic compression devices. During compressed air massage it is common to see what is taken as being edema fluid, draining from the ulcer.

Compressed air therapy can be viewed as a variant of pneumatic compression. It appears to be a safe and simple treatment modality, which, when added to standard medical and surgical management of infected diabetic ulcers, enhances ulcer healing. Further studies with this treatment modality are warranted.

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